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AstraZeneca UK Limited, AstraZeneca AB, KuDOS
Pharmaceuticals Limited, The University of Sheffield, and
MSD International Business GmbH*

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ASTRAZENECA PHARMACEUTICALS
LP, ASTRAZENECA UK LIMITED,
ASTRAZENECA AB, KUDOS
PHARMACEUTICALS LIMITED, THE
UNIVERSITY OF SHEFFIELD, and MSD
INTERNATIONAL BUSINESS GMBH

Plaintiffs,

v.

CIPLA LIMITED and CIPLA USA, INC.,

Defendants.

Civil Action No. 3:24-7346

**COMPLAINT FOR
PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH (collectively, “Plaintiffs”), by their attorneys, file this Complaint against Defendants Cipla Limited and Cipla USA, Inc. (collectively, “Cipla”), and allege the following:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, which arises out of the submission by Cipla of an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, prior to the expiration of U.S. Patent No. 8,859,562 (“the ’562 patent”); U.S. Patent No. 11,970,530 (the “’530 patent”); U.S. Patent No. 11,975,001 (the “’001 patent”); U.S. Patent No. 8,475,842 (“the ’842 patent”); and U.S. Patent No. 11,633,396 (“the ’396 patent”) (collectively, the “Patents-in-Suit”).

2. Cipla notified Plaintiffs by letter dated May 21, 2024 (“Cipla’s Notice Letter”) that it had submitted to FDA ANDA No. 219410 (“Cipla’s ANDA”), seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic olaparib tablets, 100 mg and 150 mg (“Cipla’s ANDA Product”), prior to the expiration of the ’562, ’842, and ’396 patents.

The Parties

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets.

4. Plaintiff AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

5. Plaintiff AstraZeneca AB is a limited company organized and existing under the laws of Sweden, whose registered office is at SE-151 85, Södertälje, Sweden.

6. Plaintiff KuDOS Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

7. Plaintiff The University of Sheffield is a Royal Charter company organized and existing under the laws of England and Wales, whose address is Western Bank, Sheffield S10 2TN, United Kingdom.

8. Plaintiff MSD International Business GmbH is a company with limited liability organized and existing under the laws of Switzerland, whose registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

9. On information and belief, Defendant Cipla Limited is a corporation organized and existing under the laws of India, with a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

10. On information and belief, Defendant Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in Warren, New Jersey. On information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

11. On information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Limited and is controlled by Cipla Limited.

12. On information and belief, Cipla Limited and Cipla USA, Inc. acted in concert to prepare and submit Cipla's ANDA to the FDA.

13. On information and belief, Cipla Limited and Cipla USA, Inc. know and intend that upon approval of Cipla's ANDA, Cipla Limited will manufacture Cipla's ANDA Product and Cipla Limited and Cipla USA, Inc. will directly or indirectly market, sell, and distribute Cipla's ANDA Product throughout the United States, including in New Jersey.

14. On information and belief, following any FDA approval of Cipla's ANDA, Cipla Limited and Cipla USA, Inc. will act in concert to distribute and sell Cipla's ANDA Product throughout the United States, including in New Jersey.

Jurisdiction

15. Plaintiffs incorporate each of the preceding paragraphs 1–14 as if fully set forth herein.

16. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

17. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc.

18. Cipla Limited and Cipla USA, Inc. are subject to personal jurisdiction in New Jersey because, among other things, Cipla Limited and Cipla USA, Inc. have purposefully availed themselves of the benefits and protections of New Jersey's laws such that those entities would reasonably anticipate being haled into court here. On information and belief, Cipla Limited and Cipla USA, Inc. develop, manufacture, import, market, offer to sell, and/or sell generic drugs throughout the United States, including in the State of New Jersey, and therefore transact business

within the State of New Jersey related to Plaintiffs' claims, and/or have engaged in systematic and continuous business contacts within the State of New Jersey.

19. In addition, this Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, among other things, on information and belief: (1) Cipla USA, Inc. filed Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Cipla's ANDA, Cipla Limited and Cipla USA, Inc. will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Cipla's ANDA, Cipla's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

20. This Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because those entities (1) engage in patent litigation concerning Cipla's products in this District, and (2) do not contest personal jurisdiction in this District. *See, e.g., Cubist Pharms. LLC v. Cipla USA, Inc. and Cipla Limited*, Civ. No. 19-12920, Dkt. No. 15 (D.N.J. July 2, 2019).

21. Additionally, this Court has personal jurisdiction over Cipla USA, Inc. because, on information and belief, Cipla USA, Inc. maintains its principal place of business in this District.

22. For the above reasons, it would not be unfair or unreasonable for Cipla Limited and Cipla USA, Inc. to litigate this action in this District, and the Court has personal jurisdiction over those entities here.

Venue

23. Plaintiffs incorporate each of the preceding paragraphs 1–22 as if fully set forth herein.

24. Venue is proper in this District as to Cipla Limited pursuant to 28 U.S.C. § 1391, at least because, on information and belief, Cipla Limited is a foreign corporation that may be sued in any judicial district in which it is subject to the Court’s personal jurisdiction.

25. Venue is proper in this District as to Cipla USA, Inc. pursuant to 28 U.S.C. § 1400(b), at least because, on information and belief, Cipla USA, Inc. has committed, or will commit, an act of infringement in this District, and has a regular and established place of business in this District. On information and belief, among other things, (1) Cipla filed Cipla’s ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla’s ANDA Product in the United States, including in New Jersey; and (2) upon approval of Cipla’s ANDA, Cipla will market, distribute, offer for sale, sell, and/or import Cipla’s ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Cipla’s ANDA Product in New Jersey. Further, on information and belief, Cipla USA, Inc. maintains its principal place of business in this District.

26. Venue is proper in this District as to Cipla Limited and Cipla USA, Inc. because those entities (1) engage in patent litigation concerning Cipla’s products in this District, and (2) do not contest that venue is proper in this District. *See, e.g., Cubist Pharms. LLC v. Cipla USA, Inc. and Cipla Limited*, Civ. No. 19-12920, Dkt. No. 15 (D.N.J. July 2, 2019).

Factual Background

27. LYNPARZA® is approved by FDA for the treatment of certain ovarian, breast, pancreatic, and prostate cancers. The active pharmaceutical ingredient in LYNPARZA® is olaparib, a poly (ADP-ribose) polymerase (PARP) inhibitor.

28. In Cipla's Notice Letter, Cipla states that the subject of Cipla's ANDA is olaparib tablets, 100 mg and 150 mg. In Cipla's Notice Letter, Cipla states that Cipla's ANDA was submitted under 21 U.S.C. § 355(j)(1) and § 355(j)(2)(A) and contends that Cipla's ANDA contains bioavailability and/or bioequivalence studies for Cipla's ANDA Product. On information and belief, Cipla's ANDA Product is a generic version of LYNPARZA®.

29. The purpose of Cipla's submission of Cipla's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product.

30. In Cipla's Notice Letter, Cipla stated that it had submitted Paragraph IV Certifications to FDA alleging that the '562, '842, and '396 patents were invalid, unenforceable, and/or not infringed, and that Cipla is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '562, '842, and '396 patents.

31. On April 10, 2024, the U.S. Patent and Trademark Office issued an Issue Notification for the '530 patent. The '530 patent issued on April 30, 2024. On April 17, 2024, the U.S. Patent and Trademark Office issued an Issue Notification for the '001 patent. The '001 patent issued on May 7, 2024. LYNPARZA is covered by claims of the '530 and '001 patents, and the '530 and '001 patents have been listed in connection with LYNPARZA in the FDA's Orange Book.

32. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the Patents-in-Suit.

33. In Cipla's Notice Letter, Cipla included an Offer for Confidential Access to a redacted version of Cipla's ANDA. Cipla's Offer for Confidential Access was subject to various unreasonably restrictive conditions.

34. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's Offer for Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, Cipla's ANDA and any Drug Master File referred to therein, as well as other material relevant to infringement.

35. This action is being commenced within forty-five days from the date Plaintiffs received Cipla's Notice Letter.

Count I – Infringement of the '562 Patent Under 35 U.S.C. § 271(e)(2)

36. Plaintiffs incorporate each of the preceding paragraphs 1–35 as if fully set forth herein.

37. On October 14, 2014, the USPTO duly and lawfully issued the '562 patent, entitled "Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer." A copy of the '562 patent is attached hereto as Exhibit A.

38. Plaintiff The University of Sheffield is the assignee of the '562 patent. Plaintiffs collectively possess all exclusive rights and interests in the '562 patent.

39. The '562 patent claims, *inter alia*, a method of treatment of cancer cells defective in homologous recombination (HR).

40. Methods of using LYNPARZA® are covered by one or more claims of the '562 patent, including at least claim 1 of the '562 patent, and the '562 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

41. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '562 patent was an act of infringement of the '562 patent under 35 U.S.C. § 271(e)(2)(A).

42. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe claim 1 of the '562 patent.

43. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '562 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '562 patent after approval of Cipla's ANDA.

44. The foregoing actions by Cipla constitute and/or will constitute infringement of the '562 patent, active inducement of infringement of the '562 patent, and contribution to the infringement by others of the '562 patent.

45. On information and belief, Cipla has acted with full knowledge of the '562 patent and without a reasonable basis for believing that it would not be liable for the infringement of the '562 patent, and contributing to the infringement by others of the '562 patent.

46. In Cipla's Notice Letter, Cipla did not contest infringement of claim 1 of the '562 patent on any basis other than the alleged invalidity of that claim.

47. Unless Cipla is enjoined from infringing the '562 patent, actively inducing the infringement of the '562 patent, and contributing to the infringement by others of the '562 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count II – Declaratory Judgment of Infringement of the '562 Patent

48. Plaintiffs incorporate each of the preceding paragraphs 1–47 as if fully set forth herein.

49. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding infringement and/or invalidity of the '562 patent.

50. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '562 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '562 patent, and that the claims of the '562 patent are valid and enforceable.

Count III – Infringement of the '842 Patent Under 35 U.S.C. § 271(e)(2)

51. Plaintiffs incorporate each of the preceding paragraphs 1–50 as if fully set forth herein.

52. On July 2, 2013, the USPTO duly and lawfully issued the '842 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One." A copy of the '842 patent is attached hereto as Exhibit B.

53. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '842 patent. Plaintiffs collectively possess all exclusive rights and interests in the '842 patent.

54. The '842 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising olaparib and certain excipients.

55. LYNPARZA® is covered by one or more claims of the '842 patent, including at least claim 1 of the '842 patent, and the '842 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

56. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

57. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '842 patent, recited above, either literally or under the doctrine of equivalents.

58. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe at least claim 1 of the '842 patent.

59. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '842 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval of Cipla's ANDA.

60. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '842 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '842 patent after approval of Cipla's ANDA.

61. The foregoing actions by Cipla constitute and/or will constitute infringement of the '842 patent, active inducement of infringement of the '842 patent, and contribution to the infringement by others of the '842 patent.

62. On information and belief, Cipla has acted with full knowledge of the '842 patent and without a reasonable basis for believing that it would not be liable for infringing the '842 patent, actively inducing infringement of the '842 patent, and contributing to the infringement by others of the '842 patent.

63. Unless Cipla is enjoined from infringing the '842 patent, actively inducing infringement of the '842 patent, and contributing to the infringement by others of the '842 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count IV – Declaratory Judgment of Infringement of the '842 Patent

64. Plaintiffs incorporate each of the preceding paragraphs 1–63 as if fully set forth herein.

65. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding validity and/or infringement of the '842 patent.

66. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '842 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '842 patent, and that the claims of the '842 patent are valid and enforceable.

Count V – Infringement of the '396 Patent Under 35 U.S.C. § 271(e)(2)

67. Plaintiffs incorporate each of the preceding paragraphs 1–66 as if fully set forth herein.

68. On April 25, 2023, the USPTO duly and lawfully issued the '396 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One." A copy of the '396 patent is attached hereto as Exhibit C.

69. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '396 patent. Plaintiffs collectively possess all exclusive rights and interests in the '396 patent.

70. The '396 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising olaparib and certain excipients.

71. LYNPARZA® is covered by one or more claims of the '396 patent, including at least claim 1 of the '396 patent, and the '396 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

72. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '396 patent was an act of infringement of the '396 patent under 35 U.S.C. § 271(e)(2)(A).

73. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '396 patent, recited above, either literally or under the doctrine of equivalents.

74. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe at least claim 1 of the '396 patent.

75. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '396 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval of Cipla's ANDA.

76. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '396 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '396 patent after approval of Cipla's ANDA.

77. The foregoing actions by Cipla constitute and/or will constitute infringement of the '396 patent, active inducement of infringement of the '396 patent, and contribution to the infringement by others of the '396 patent.

78. On information and belief, Cipla has acted with full knowledge of the '396 patent and without a reasonable basis for believing that it would not be liable for infringing the '396 patent, actively inducing infringement of the '396 patent, and contributing to the infringement by others of the '396 patent.

79. Unless Cipla is enjoined from infringing the '396 patent, actively inducing infringement of the '396 patent, and contributing to the infringement by others of the '396 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count VI – Declaratory Judgment of Infringement of the '396 Patent

80. Plaintiffs incorporate each of the preceding paragraphs 1–79 as if fully set forth herein.

81. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding validity and/or infringement of the '396 patent.

82. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '396 patent, will infringe, induce the infringement

of, and contribute to the infringement by others of the '396 patent, and that the claims of the '396 patent are valid and enforceable.

Count VII – Infringement of the '001 Patent Under 35 U.S.C. § 271(e)(2)

83. Plaintiffs incorporate each of the preceding paragraphs 1–82 as if fully set forth herein.

84. On May 7, 2024, the United States Patent and Trademark Office (the “USPTO”) duly and lawfully issued the '001 patent, entitled “Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One.” A copy of the '001 patent is attached hereto as Exhibit D.

85. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '001 patent. Plaintiffs collectively possess all exclusive rights and interests in the '001 patent.

86. The '001 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One, known by the international nonproprietary name olaparib, and certain excipients.

87. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

88. LYNPARZA® is covered by one or more claims of the '001 patent, including at least claim 1 of the '001 patent, and the '001 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

89. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '001 patent.

90. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's

ANDA Product prior to the expiration of the '001 patent was an act of infringement of the '001 patent under 35 U.S.C. § 271(e)(2)(A).

91. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '001 patent, either literally or under the doctrine of equivalents.

92. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe at least claim 1 of the '001 patent.

93. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '001 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval of Cipla's ANDA.

94. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '001 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '001 patent after approval of Cipla's ANDA.

95. The foregoing actions by Cipla constitute and/or will constitute infringement of the '001 patent, active inducement of infringement of the '001 patent, and contribution to the infringement by others of the '001 patent.

96. On information and belief, Cipla has acted with full knowledge of the '001 patent and without a reasonable basis for believing that it would not be liable for infringing the '001 patent, actively inducing infringement of the '001 patent, and contributing to the infringement by others of the '001 patent.

97. Unless Cipla is enjoined from infringing the '001 patent, actively inducing infringement of the '001 patent, and contributing to the infringement by others of the '001 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count VIII – Declaratory Judgment of Infringement of the '001 Patent

98. Plaintiffs incorporate each of the preceding paragraphs 1–97 as if fully set forth herein.

99. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding validity and/or infringement of the '001 patent.

100. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '001 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '001 patent, and that the claims of the '001 patent are valid and enforceable.

Count IX – Infringement of the '530 Patent Under 35 U.S.C. § 271(e)(2)

101. Plaintiffs incorporate each of the preceding paragraphs 1–100 as if fully set forth herein.

102. On April 30, 2024, the United States Patent and Trademark Office (the "USPTO") duly and lawfully issued the '530 patent, entitled "Methods of Treating Homologous Recombination Deficient Cancer." A copy of the '530 patent is attached hereto as Exhibit E.

103. Plaintiff AstraZeneca AB is the assignee of the '530 patent. Plaintiffs collectively possess all exclusive rights and interests in the '530 patent.

104. The '530 patent claims, *inter alia*, a method for treating ovarian cancer, fallopian tube cancer, primary peritoneal cancer, and/or pancreatic cancer in a subject, the method comprising

administering to the subject a therapeutically effective amount of bevacizumab, and a therapeutically effective amount of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One (olaparib).

105. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

106. Methods of using LYNPARZA® are covered by one or more claims of the '530 patent, including at least claim 1 of the '530 patent, and the '530 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

107. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '530 patent.

108. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '530 patent was an act of infringement of the '530 patent under 35 U.S.C. § 271(e)(2)(A).

109. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '530 patent, either literally or under the doctrine of equivalents.

110. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe at least claim 1 of the '530 patent.

111. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '530 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval of Cipla's ANDA.

112. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '530 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '530 patent after approval of Cipla's ANDA.

113. The foregoing actions by Cipla constitute and/or will constitute infringement of the '530 patent, active inducement of infringement of the '530 patent, and contribution to the infringement by others of the '530 patent.

114. On information and belief, Cipla has acted with full knowledge of the '530 patent and without a reasonable basis for believing that it would not be liable for infringing the '530 patent, actively inducing infringement of the '530 patent, and contributing to the infringement by others of the '530 patent.

115. Unless Cipla is enjoined from infringing the '530 patent, actively inducing infringement of the '530 patent, and contributing to the infringement by others of the '530 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count X – Declaratory Judgment of Infringement of the '530 Patent

116. Plaintiffs incorporate each of the preceding paragraphs 1–115 as if fully set forth herein.

117. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding the validity and/or infringement of the '530 patent.

118. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '530 patent, will infringe, induce the infringement

of, and contribute to the infringement by others of the '530 patent, and that the claims of the '530 patent are valid and enforceable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

1. A judgment that the Patents-in-Suit have been infringed under 35 U.S.C. § 271(e)(2) by Cipla's submission to the FDA of Cipla's ANDA;
2. A judgment that the Patents-in-Suit are valid and enforceable;
3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval of Cipla's ANDA and for Cipla to make, use, offer for sale, sell, market, distribute, or import Cipla's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity.
4. A preliminary and permanent injunction pursuant to 35 U.S.C. § 371(e)(4)(B) enjoining Cipla, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

5. An order pursuant to this Court's equitable power that the effective date of any final approval of Cipla's ANDA shall be a date that is not earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;
6. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration dates of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;
7. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
8. An award of Plaintiffs' costs and expenses in this action; and
9. Such further and other relief as this Court may deem just and proper.

Dated: June 28, 2024

Respectfully submitted,

s/Charles H. Chevalier

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